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Atty Dkt. No. 1631.002 PATENT

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7/18/UI_ Date Susan Lallont

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

BARNETT et al.

Serial No.: 09/475,704

Art Unit: 1633

Filing Date: December 30, 1999

Examiner: B. Whiteman

Title:

POLYNUCLEOTIDES ENCODING ANTIGENIC HIV TYPE C

POLYPEPTIDE, POLYPEPTIDES AND USES THEREOF

RESPONSE TO REQUIREMENT FOR RESTRICTION

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

This is in response to the Restriction Requirement dated April 18, 2001 (Paper No. 8). Submitted herewith is a petition for a two-month extension of time and appropriate fee, making a response due on or before July 18, 2001. The Examiner therein required election of one of the following groups of claims:

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Groups I and II: Claims 1, 24-43, 49-60 and 62-66, drawn to an expression cassette comprising polynucleotide sequences encoding Gag;

Group III. Claims 2-9 drawn to an expression cassette comprising polynucleotide sequences encoding Gag;

Group IV. Claims 2, 4, 6-9 drawn to an expression cassette comprising polynucleotide sequences encoding Gag;

Group V. Claims 11 and 44-46 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

Group VI. Claim 12 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

Group VII. Claim 13 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

Group VIII. Claim 14 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

Group IX. Claims 15 and 23 Claim 13 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

Group X. Claim 16 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

Group XI. Claim 17 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

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Group XII. Claim 18 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

Group XIII. Claim 19 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

Group XIV. Claim 20 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

Group XV. Claims 21 and 23 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

Group XVI. Claim 22 drawn to an expression cassette comprising polynucleotide sequences encoding Env;

Group XVII. Claims 47 and 48 drawn to compositions comprising expression cassettes of claim 1 and a Gag polypeptide;

Group XVIII. Claim 61 drawn to a method of generating an immune response using the expression cassette of claim 1.

Applicants hereby elect to prosecute the claims of Group I, claims 1, 24-43, 49-60 and 62-66, **with traverse**. In support of the restriction requirement, the Examiner asserts that the claims of each group are patentably distinct. However, it is unclear to Applicants how claims 1, 24-43, 49-60 and 62-66 can be included in two allegedly separate Groups: Groups I and II. It is impossible for these claims to be "patentably distinct" from themselves.

Further, Groups I through XVII are <u>all</u> classified in Class 435, subclass 320.1, class 536, subclass 23.1 in the U.S. Patent Classification System and therefore are subject to all the same definitions, rules and, moreover, searches. Accordingly, they should be examined together and it would not constitute an undue burden for the Examiner to do so.

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It is also entirely unclear to the Applicants how independent, generic claim 11 (Group V) can be "patentably distinct" from dependent claims 12, 14, 15 and 23 (Groups VI, VII, VII, and IX) or how generic claim 17 (Group XI) can be "patentably distinct" from dependent claims 18-21 and 23 (Groups XII through XV).

Applicants submit that the outstanding Restriction Requirement confuses restriction and election practice. In the pending case, at best, an election (not restriction) as between the Gag and Env sequences may be appropriate. Certainly, Restriction as between polynucleotide sequences encoding HIV polypeptides is entirely inappropriate. The MPEP clearly states that where the claims define the same essential characteristics of a single disclosed embodiment of an invention, varying in scope or breadth of definition of the same disclosed subject matter, a restriction requirement is improper. (see, MPEP 806.03) As discussed above, Groups I through XVII define essentially the same subject matter, as evidenced by the classification of all these Groups in Class 435, subclass 320.1, class 536, subclass 23.1. Thus, applicants submit that the Restriction Requirement be redefined to combine Groups I to XVII, drawn to polynucleotide sequences encoding HIV Gag or Env polypeptides and compositions comprising these polynucleotides sequences. As acknowledged by the Examiner, the search required for these Groups is the same and, indeed, Applicants have provided the sequences on which to base these searches. Therefore, examination of these allegedly distinct inventions in one application would not only not place an undue burden on the Examiner, but would actually save the Examiner time.

Applicants expressly reserve their right under 35 USC §121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application. Further, should the Examiner make the requirement final, Applicants reserve the right to appeal.

In response to the various species election requirements, Applicants elect CHO cells of claim 29; Sf9 cells of claim 32; T-cells of claim 37; and CMV of claim 26. It is to be understood that this election of species is for the purposes of preliminary search

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and examination only, and that upon allowance of a generic claim, applicants will be entitled to consideration of claims to the additional species.

The proposed groupings of the claims are confusing and any determination of distinctness of independence of the claimed invention(s) by the Examiner may have later ramifications during prosecution of this and related applications. For example, Applicants cannot understand what ramifications the proposed restriction requirement would have relative to double patenting issues during prosecution of the non-elected claims if they were filed and prosecuted in related applications (see, MPEP 806).

Further clarification is respectfully requested before the Examiner takes further action in this application. The Examiner is requested to review Applicants' traverse of the restriction requirement and to contact the Applicants.

Respectfully submitted,

Date: July 18, 200/

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Dahna S. Pasternak

Registration No. 41,411

ROBINS & PASTERNAK LLP 90 Middlefield Road, Suite 200 Menlo Park, CA 94025

Telephone: (650) 325-7812

Fax: (650) 325-7823